COMPENSATION FOR VARIABILITY IN SPECIFIC BINDING IN QUANTITATIVE ASSAYS

ABSTRACT OF THE DISCLOSURE

Methods for quantitatively measuring the amount of an analyte of interest in a fluid sample are disclosed. The methods involve providing a membrane having an application point, a contact region comprising analyte-binding particles, a sample capture zone, and a control capture zone, where the contact region is between the application point and the sample capture zone, and the sample capture region is between the contact region and the control capture zone. In the assays, a fluid allows transport components of the assay by capillary action through the contact region, to and through the sample capture zone and subsequently to and through the control capture zone. In a "sandwich assay" embodiment, the amount of analyte in the fluid sample is related to a corrected analyte-binding particle amount, which can be determined, for example, as a ratio of the amount of analyte-binding particles in the sample capture zone and the amount of analyte-binding particles in the control capture zone. In a "competitive assay" embodiment, the membrane has an application point, a contact region comprising analyte-coated particles, a sample capture zone, and a control capture zone, where the contact region is between the application point and the sample capture zone, and the sample capture zone is between the contact region and the control capture zone. In this "competitive assay" embodiment, the amount of analyte in the fluid sample is inversely related to a corrected analyte-coated particle amount, which can be determined, for example, as a ratio of the amount of analyte-coated particles in the sample capture zone and the amount of analyte-coated particles in the control capture zone.